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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,250	02/01/2001	David Berd	1225/1G584US2	8162

7590 04/09/2003

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/776,250	Berd
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *13-56* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *16, 17, and 21-56* is/are allowed.

6) ☒ Claim(s) *13-15 and 18-20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received:
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1-12 have been canceled. Claims 13, 16-20 have been amended. Claims 25-56 have been added.

2. Claim 15 is objected to for being dependent on a canceled claim.

3. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 embodies the method of claim 13 wherein the adjuvants are selected from a group, however, claim 13 specifies the method without any adjuvant.

Claim 13 recites a method step comprising the administration of a composition comprising haptenized or non-haptenized tumor cells or tumor dell extracts; and the further limitation (b)wherein said tumor cells or tumor cell extracts are conjugated to a hapten. It is unclear how the limitations of administering a non-haptenized tumor cell can have the limitation of being conjugated to a hapten.

4. Claims 13, 15, 18, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Berd et al (Ann NY Academy Sci, 1993, Vol. 690, pp. 147-152) or Berd et al (WO 98/14206; reference 10 of the IDS filed June 6, 2001) or Berd et al (WO 96/40173, reference 11 of the IDS filed June 6, 2001)..

Berd et al (1993) disclose a method of inducing an anti-tumor response in a human patient comprising the administration of 1 X 10^7 to 12 X 10^7 autologous, irradiated (2500 rads) dinitrophenyl conjugated melanoma cells. Twenty eight days later, cyclophosphamide was administered, fulfilling the requirement of administering the composition prior to the

administration of cyclophosphamide. The instant claim is drawn to a method and a composition comprising 2 X 10^5 to 2.5 X 10^6 irradiated, haptenized tumor cells which reads on compositions comprising a greater number of cells.

Berd et al (WO 98/14206) disclose a method of treating a patient suffering from melanoma, ovarian cancer, breast cancer, colon cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, or leukemia (page 6, lines 21-30) comprising the administration of a composition comprising 2 X 10^5 to 2.5 X 10^7 irradiated (page 8, lines 25-29), haptenized (page 9, lines 3-25) tumor cells. The instant claims are drawn to cell compositions comprising 2 X 10^5 to 2.5 X 10^6 tumor cells which falls within the disclosed range of 2 X 10^5 to 2.5 X 10^7.

Berd et al Berd et al (WO 96/40173) disclose a method of treating melanoma, breast, lung, colon, kidney and prostate cancer comprising the administration of tumor cell or tumor cell extract, wherein said tumor cell extract may be haptenized or irradiated prior to administration. Berd et al disclose a composition consisting of 5 X 10 6 haptenized, irradiated tumor cells. Berd et al further disclose that cancer cells of a patient may be conjugated to a hapten, followed by isolation of membranes (page 25, lines 1-4), therefore, Berd et al disclose cell extracts comprising 2 X 10^5 to 2.5 X 10^6 cell equivalents per dose. Berd et la disclose that the tumor cell extract comprises tumor cell polypeptides as tumor cell peptide may be extracted from haptenized cells (page 26, lines 19-24).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.d. 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 13, 15, 18, 19 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 9, 10 of copending Application No. 09/304,859. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of inducing an anti-tumor response comprising the administration to a patient in need thereof a "therapeutically effective" amount of a tumor cell or tumor cell extract embodies the instant claims drawn to a composition and a method as the '859 application discloses a therapeutically effective amount of haptenized, irradiated tumor cell or tumor cell extract as containing 105 cell or cell equivalents per dose (page 15, lines 25-31).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 13, 15, 18, 19 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 7, 11, 16, 20, 21, 25, 53, 54 and 55 of copending Application No. 09/025,012. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '012 application both claims and teaches therapeutically effective amounts of haptenized tumor cell equivalents of 10^4 to 7.5×10^6 as well as 2.4×10^6 to 7.5×10^6 cell equivalents per dose for the treatment of a variety of solid and non solid malignancies as listed on page 18, lines 1-17 of the '012 application).

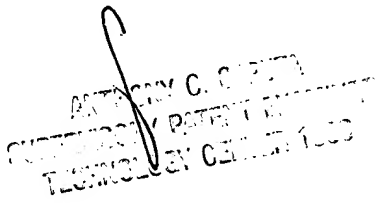
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
April 7, 2003